



(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
16.06.2021 Bulletin 2021/24

(51) Int Cl.:
A61M 1/36 ^(2006.01) **A61M 39/10** ^(2006.01)

(21) Application number: **19216147.9**

(22) Date of filing: **13.12.2019**

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR
Designated Extension States:
BA ME KH MA MD TN

(72) Inventor: **VERNIN, Guillaume**
F-69330 MEYZIEU (FR)

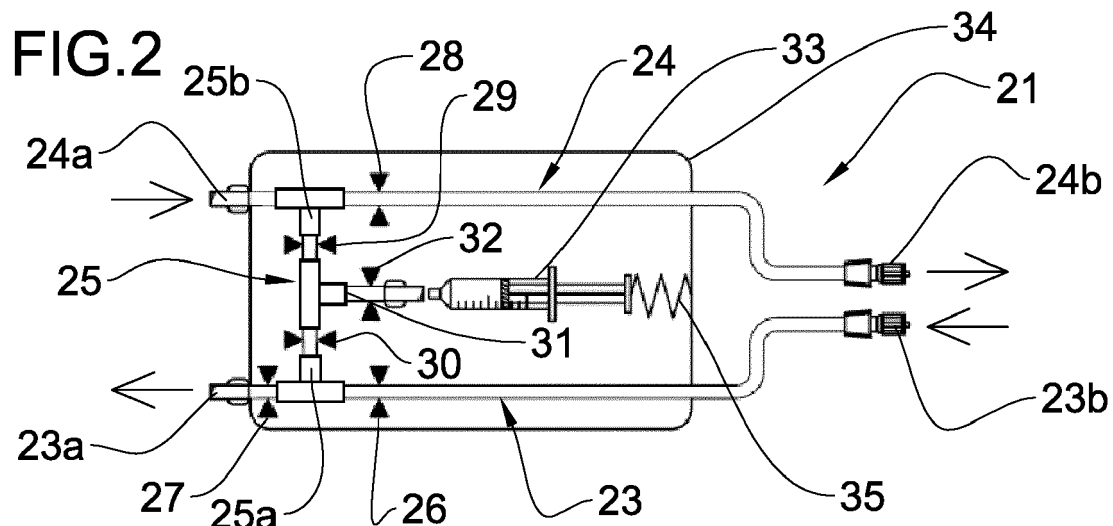
(74) Representative: **PGA S.p.A., Milano, Succursale di Lugano**
Via Castagnola, 21c
6900 Lugano (CH)

(71) Applicant: **Gambro Lundia AB**
226 43 Lund (SE)

(54) **ADD-ON MODULE FOR AN APPARATUS FOR EXTRACORPOREAL TREATMENT OF BLOOD AND BLOOD SET PROVIDED WITH SAID ADD-ON MODULE**

(57) An add-on module for an apparatus for extracorporeal treatment of blood is configured to be placed in-line between a main portion (22) of the apparatus (1) and a vascular access of a patient (P) and comprises: a substantially H-shaped conduits assembly comprising a withdrawal conduit (23), a return conduit (24) and a bridging conduit (25) connecting the withdrawal conduit (23) to the return conduit (24). The withdrawal conduit (23) is

connectable upstream and downstream to a withdrawal line (6) of the apparatus (1), the return conduit (24) is connectable upstream and downstream to a return line (7) of the apparatus (1). A plurality of valves (26, 27, 28, 29, 30, 31) operate on the withdrawal conduit (23), on the return conduit (24) and on the bridging conduit (25) and are configured to divert a flow of liquid and/or blood without disconnecting the patient (P).



Description

TECHNICAL FIELD

[0001] The invention relates to an add-on module for an apparatus for extracorporeal treatment of blood and to a blood set for an apparatus for extracorporeal treatment of blood provided with this add-on module.

[0002] Extracorporeal blood treatment involves removing blood from a patient, treating the blood externally to the patient, and returning the treated blood to the patient. Extracorporeal blood treatment is typically used to extract undesirable matter or molecules from the patient's blood and add desirable matter or molecules to the blood. Extracorporeal blood treatment is used with patients unable to effectively remove matter from their blood, such as when a patient has suffered temporary or permanent kidney failure. These patients and other patients may undergo extracorporeal blood treatment to add or remove matter to their blood, to maintain an acid/base balance or to remove excess body fluids, or to perform extracorporeal gas exchange processes, for example.

[0003] For instance, in a haemodialysis treatment a patient's blood and a treatment liquid approximately isotonic with blood flow are circulated in a respective compartment of haemodialyser, so that, impurities and undesired substances present in the blood (urea, creatinine, etc.) may migrate by diffusive transfer from the blood into the treatment liquid. The ion concentration of the treatment liquid is chosen so as to correct the ion concentration of the patient's blood. In a treatment by haemodiafiltration, a convective transfer by ultrafiltration, resulting from a positive pressure difference created between the blood side and the treatment-liquid side of the membrane of a haemodiafilter, is added to the diffusive transfer obtained by dialysis. Hemoperfusion, oxygenation or decarboxylation treatments are also known.

[0004] A vascular access is used to remove the patient's blood so that it is filtered through the blood treatment unit (dialyzer, filter) and then returned to the patient. In case of chronic treatments, the vascular access may be arterio-venous. Two needles may be inserted into the vein, one to draw blood and one to return it. The orientation of the needles takes the normal flow of the blood into account. The "arterial" needle draws blood from the "upstream" location while the "venous" needle returns blood "downstream". In case of acute treatments, the vascular access may be veno-venous, i.e. using a double-lumen catheter inserted in a central vein. The blood treatment unit comprises pressure monitoring devices, as to check, for example, for circuit obstructions.

BACKGROUND OF THE INVENTION

[0005] In the field of extracorporeal blood treatments and therapies, some problems reported by users are issues at the vascular access. Access Extremely Negative

(AEN) is one of the most encountered alarm in the field, mainly linked to catheter tip stuck against blood vessel's wall or, more rarely, to clots obstructing the access way of the catheter. When this alarm relates to catheter positioning inside the vein, the nurse has to get the access pressure back closer to an atmospheric level, e.g. through the use of a Y-connector connected to the access line, unstick the catheter tip from the vein wall and then try to move the catheter inside the vein and resume the treatment.

[0006] Another drawback is that at the end of the treatment, when blood is to be returned to the patient, one operator has to disconnect the patient access and connect a saline bag to the set's access line, in aseptic conditions, and another operator has to operate on the monitor of the machine in non-aseptic conditions. Therefore, two operators are needed for one patient.

[0007] Another drawback is that, as per the blood return described above, both saline and blood recirculation procedures currently require sterile and non-sterile interventions and the manual connection of supplementary devices (Y-connector, saline bag).

[0008] In all the cases detailed above, the operator has to handle the vascular access, to disconnect and eventually reconnect the same to the patient. All this implies operator workload and increased probability of occurrence for non-aseptic handling.

[0009] Furthermore, the use of a Y-connector connected to the access line involves further risks. On the access side, the user may forget to clamp the Y saline line prior to resuming the treatment. In case of blood pump stop and slightly negative patient access pressure, the saline bag content would be sucked into the catheter, causing air ingress leading to set clotting (or potentially air embolism). Additional modules, configured to be placed in-line between the blood treatment apparatus and the patient vascular access and configured to divert the flow of blood without necessarily disconnecting the patient, are also known.

[0010] For instance, document US 3, 626, 938 discloses a shunt valve device which is designed to be mounted permanently on a body member of a person and permanently connected to the artery and vein of the person. The device is provided with valve means for selectively connecting the artery and vein to an artificial kidney or the like. The device further has rotary shunt means for directing the flow of blood back to the body member when the device is not operatively connected to the artificial kidney.

[0011] Document US 5,894,011 discloses a device for selectively controlling the direction of blood flow to and from the patient during hemodialysis. The device comprises two interlocking disks that rotate in relation to each other without separating. The two disks have fluid fittings that allow the blood lines attached to the patient to connect to one of the disks and the blood inlet and outlet for the hemodialysis machine to connect to the other. The center of each fluid fitting is a channel that aligns to a

corresponding channel in the other disk. The disks rotate between two fixed relative positions, referred to herein as preferred alignments. The preferred alignments are such that the line drawing blood from the patient in the first preferred alignment becomes the line returning blood to the patient in the second preferred alignment, and the line returning blood to the patient in the first preferred alignment becomes the line drawing blood from the patient in the second preferred alignment. A bypass channel allows blood to flow from the outlet to the inlet of the hemodialysis machine when the device is in neither of its two preferred alignments.

[0012] These devices allow a limited number of flow path configurations and, due to their structure and geometry of the ducts, may cause pressure drops and/or clotting.

[0013] It is therefore an object of the present invention to provide an add-on module for an apparatus for extracorporeal treatment of blood, wherein the add-on module is configured to divert the flow of blood or other fluid/s in order to perform a plurality of procedures (e.g. all the steps of the treatment, pre and post treatment and possible troubleshooting procedures) without necessarily disconnecting the patient.

[0014] It is an object of the present invention to provide an add-on module which may be easily interposed between the apparatus for extracorporeal treatment of blood and the patient, featuring various functional components and able to be set in a plurality of configurations to perform the plurality of procedures.

[0015] In particular, it is an object providing an add-on module able to provide easy and safe AEN troubleshooting, blood return at the treatment end, blood recirculation, saline recirculation.

[0016] It is a further object providing an add-on module allowing to control its configurations in automated manner.

[0017] It is also an object of the present invention to provide an add-on module enabling offering the add-on features as a supplemental option with respect to the apparatus.

[0018] It is a further object providing an add-on module allowing a single person to handle the patient's vascular access in safe manner and in aseptic conditions.

[0019] It is a further object providing an add-on module offering the possibility to have some commands located conveniently nearby the patient access.

[0020] It is a further object providing an add-on module offering the possibility to operate disinfection procedures in aseptic conditions.

[0021] It is a further object providing an add-on module which is structurally simple, cost effective and reliable.

[0022] It is a further object providing an add-on module able to prevent clotting and/or to avoid high pressure losses and/or requiring minimal amounts of fluid needed for flushing said add-on module.

SUMMARY

[0023] At least one of the above objects is substantially reached by an add-on module for an apparatus for extracorporeal treatment of blood and by an apparatus for extracorporeal treatment of blood according to one or more of the appended claims.

[0024] An add-on module for an apparatus for extracorporeal treatment of blood, an apparatus for extracorporeal treatment of blood and a method for diverting a flow of liquid and/or blood in an apparatus for extracorporeal treatment of blood according to aspects of the invention and capable of achieving one or more of the above objects are here below described.

[0025] A 1st aspect concerns an add-on module for an apparatus for extracorporeal treatment of blood. The add-on module is configured to be placed in-line between a blood set of an apparatus for extracorporeal treatment of blood and a vascular access of a patient. The add-on module comprises: a substantially H-shaped conduits assembly comprising a withdrawal conduit, a return conduit and a bridging conduit connecting the withdrawal conduit to the return conduit; wherein the withdrawal conduit is connectable upstream and downstream to a withdrawal line of the blood set, wherein the return conduit is connectable upstream and downstream to a return line of the blood set; a plurality of valves operating on the withdrawal conduit and/or on the return conduit and/or on the bridging conduit and configured to divert a flow of liquid and/or blood without disconnecting the patient.

[0026] A 2nd aspect concerns a blood set for an apparatus for extracorporeal treatment of blood comprising: a blood treatment unit; an extracorporeal blood circuit coupled to the blood treatment unit and comprising a blood withdrawal line and a blood return line connectable to a vascular access of a patient; an add-on module according to the preceding 1st aspect or to one or more of the following aspects, wherein the add-on module is placed or is configured to be placed in-line between a main portion of the blood set of apparatus for extracorporeal treatment of blood and the vascular access of the patient. The apparatus comprises a blood pump configured to be coupled to a pump section of the extracorporeal blood circuit.

[0027] In a further independent aspect, an apparatus for extracorporeal treatment of blood is provided comprising the blood set of the previous aspect.

[0028] A 3rd aspect concerns a method for diverting a flow of liquid and/or blood in an apparatus for extracorporeal treatment of blood without disconnecting the patient, comprising: placing in-line an add-on module between the apparatus for extracorporeal treatment of blood and a vascular access of a patient, wherein the add-on module is according to the preceding 1st aspect or to one or more of the following aspects.

[0029] In a 4th aspect according to any one of the preceding aspects, the withdrawal conduit is substantially parallel to the return conduit.

[0030] In a 5th aspect according to any one of the preceding aspects, the bridging conduit is transversal, optionally, perpendicular to the withdrawal conduit and to the return conduit.

[0031] In a 6th aspect according to the preceding aspects, the withdrawal conduit and/or the return conduit and/or the bridging conduit is/are tubes, optionally of plastic, optionally straight.

[0032] In a 7th aspect according to any one of the preceding aspects, the plurality of valves comprises at least a withdrawal valve operating on the withdrawal conduit, at least a return valve operating on the return conduit and at least a bridging valve operating on the bridging conduit.

[0033] In an 8th aspect according to any one of the preceding aspects, the valves of the plurality of valves are clamps.

[0034] In a 9th aspect according to the preceding aspect 7 or 8, said at least a withdrawal valve comprises a first withdrawal valve and a second withdrawal valve operating on the withdrawal conduit.

[0035] In a 10th aspect according to the preceding aspect 9, the first withdrawal valve and the second withdrawal valve are placed on opposite sides with respect to a junction of the bridging conduit to the withdrawal conduit.

[0036] In a 11th aspect according to the preceding aspect 9 or 10, the first withdrawal valve is placed upstream, with respect to a flow of blood during treatment, a junction of the bridging conduit to said withdrawal conduit.

[0037] In a 12th aspect according to the preceding aspect 9, 10 or 11, the second withdrawal valve is placed downstream, with respect to a flow of blood during treatment, a junction of the bridging conduit to said withdrawal conduit.

[0038] In a 13th aspect according to aspect 7 or to any one of the preceding aspects 8 to 12 when according to aspect 7, the return valve is placed downstream a junction of the bridging conduit to the return conduit with respect to a flow of blood during treatment.

[0039] In a 14th aspect according to aspect 7 or to any one of the preceding aspects 8 to 12 when according to aspect 7, the return valve comprises a first return valve and a second return valve operating on the return conduit.

[0040] In a 15th aspect according to the preceding aspect 14, the first return valve and the second return valve are placed on opposite sides with respect to a junction of the bridging conduit to the return conduit.

[0041] In a 16th aspect according to the preceding aspect 14 or 15, the first return valve is placed downstream, with respect to a flow of blood during treatment, a junction of the bridging conduit to said return conduit.

[0042] In a 17th aspect according to the preceding aspect 14, 15 or 16, the second return valve is placed upstream, with respect to a flow of blood during treatment, a junction of the bridging conduit to said return conduit.

[0043] In a 18th aspect according to aspect 7 or to any one of the preceding aspects 8 to 17 when according to aspect 7, said at least a bridging valve comprises a first

bridging valve and a second bridging valve operating on the bridging conduit.

[0044] In a 19th aspect according to the preceding aspect 18, the first bridging valve is placed closer to the return conduit (closer than the second bridging valve) and the second bridging valve is placed closer to the withdrawal conduit (closer than the first bridging valve).

[0045] In a 20th aspect according to the preceding aspect 18 or 19, the bridging conduit has an access point located between the first bridging valve and the second bridging valve and suitable to connect a liquid source; optionally the access point comprises an access valve.

[0046] In a 21st aspect according to the preceding aspect 20, the liquid source is a saline source.

[0047] In a 22nd aspect according to the preceding aspect 20 or 21, the liquid source is a syringe, e.g. of 50 ml, or a bag, e.g. of 500 ml.

[0048] In a 23rd aspect according to the preceding aspect 20 or 21 or 22, the add-on module comprises a liquid source, optionally a syringe or a bag, connected or connectable to the access point.

[0049] In a 24th aspect according to any of the preceding aspects 1 to 23, the add-on module comprises a holder configured to hold the substantially H-shaped conduits assembly and the plurality of valves, optionally the holder has seats to accommodate the substantially H-shaped conduits assembly and the plurality of valves.

[0050] In a 25th aspect according to the preceding aspects 24 when according to aspect 22 or 23, the holder is configured to hold the liquid source, optionally the syringe or the bag, optionally the holder has seats to accommodate the liquid source, optionally the syringe or the bag; optionally, the holder comprising a device for pressurizing the liquid source, optionally the syringe, like a spring or an actuator, or the bag.

[0051] In a 26th aspect according to any of the preceding aspects 1 to 25, the add-on module is at least in part disposable.

[0052] In a 27th aspect according to the preceding aspect 7 or to any of aspects 8 to 26 when according to aspect 7, the plurality of valves is configured to be arranged at least in a treatment configuration, in which said at least a withdrawal valve and said at least a return valve are open and said at least a bridging valve is closed, to perform treatment of the patient.

[0053] In a 28th aspect according to the preceding aspect 9 or to any one of the preceding aspects 10 to 27 when according to aspect 9, the plurality of valves is configured to be arranged at least in a recirculation configuration, in which the return valve is closed, the first withdrawal valve is closed, the second withdrawal valve is open and said at least a bridging valve is open, so that blood or liquid recirculates in the blood treatment unit of the apparatus without disconnecting the patient.

[0054] In a 29th aspect according to the preceding aspect 18 or to any one of the preceding aspects 19 to 28 when according to aspect 18, the plurality of valves is configured to be arranged in a return branch flushing con-

figuration, in which the first bridging valve is open, the second bridging valve is closed and the liquid source is connected to the access point to inject liquid and flush a branch of the return conduit placed downstream a junction of the bridging conduit to the return conduit and optionally to flush a catheter at the vascular access of a patient.

[0055] In a 30th aspect according the preceding aspect 29, in the return branch flushing configuration, a monitor valve on the blood return line (located between the apparatus and the add-on module) is closed or, when aspect 18 is according to aspect 14, the second return valve is closed; wherein the first withdrawal valve, the second withdrawal valve, the return valve (or the first return valve) and the access valve are open.

[0056] In a 31st aspect according the preceding aspect 18 or to any one of the preceding aspects 19 to 30 when according to aspect 18, the plurality of valves is configured to be arranged in a withdrawal branch flushing configuration, in which the first bridging valve is closed, the second bridging valve is open and the liquid source is connected to the access point to inject liquid and flush a branch of the withdrawal conduit placed upstream a junction of the bridging conduit to the withdrawal conduit and optionally to flush a catheter at the vascular access of a patient.

[0057] In a 32nd aspect according the preceding aspect 31, in the withdrawal branch flushing configuration, the second withdrawal valve is closed.

[0058] In a 33rd aspect according the any of the preceding aspects 1 to 32, the valves of the plurality of valves are operatively connected or connectable to a control unit, optionally of the apparatus for extracorporeal treatment of blood, and/or the add-on module comprises a control unit operatively connected to the plurality of valves; the control unit being configured for commanding, optionally automatically, the configurations of the plurality of valves.

[0059] In a 34th aspect according to the preceding aspect 33, the add-on module is connected or configured to be connected to the control unit of the apparatus for extracorporeal treatment of blood, optionally through wired or wireless communication.

[0060] In a 35th aspect according to any of the preceding aspects 1 to 34, the add-on module comprises a power supply or is connected to a power supply of the apparatus for extracorporeal treatment of blood.

[0061] In a 36th aspect according to any of the preceding aspects 1 to 35, the add-on module comprises an attachment device configured to install said add-on module, e.g. to clothing of a patient or to a bed for the patient or to a main portion of the apparatus for extracorporeal treatment of blood, optionally in a removable manner.

[0062] In a 37th aspect according to any of the preceding aspects 1 to 36, the add-on module comprises quick connectors, optionally Luer connectors, placed at extremities of the withdrawal conduit and of the return conduit.

[0063] In a 38th aspect according to any of the preceding aspects 1 to 36, the add-on module comprises a further access point on the return conduit, e.g. for calcium infusion.

[0064] In a 39th aspect according to any of the preceding aspects 1 to 37, the add-on module comprises at least one sensor active on the H-shaped conduits assembly, optionally on the return conduit and/or on the withdrawal conduit and/or on the bridging conduit; said at least one sensor being connected or configured to be connected to a control unit of the apparatus for extracorporeal treatment of blood or of the add-on module; said at least one sensor may be a pressure sensor, a flowmeter, an air detector.

[0065] In a 40th aspect according to one or more of the previous aspects 7 to 23, a control unit of the apparatus for extracorporeal treatment of blood or of the add-on module is configured for commanding execution of a task for diverting a flow of liquid and/or blood, said task or the method for diverting a flow of liquid and/or blood comprises the following steps:

- keeping said at least a withdrawal valve, optionally the first withdrawal valve and the second withdrawal valve, open and said at least a return valve open and keeping said at least a bridging valve, optionally the first bridging valve and the second bridging valve, closed to perform treatment of the patient;
- optionally, opening regularly the first bridging valve and the second bridging valve and the access valve, to flush with fluid and prevent coagulation; or opening regularly the first bridging valve and the second bridging valve while the access valve is closed, to create a short recirculation and prevent coagulation.

[0066] In a 41st aspect according to the previous aspect, in case of Access Extremely Negative (AEN) alarm, said task or the method for diverting a flow of liquid and/or blood comprises the following steps:

- stopping the blood pump;
- optionally, opening the second bridging valve and the access valve enabling liquid to be sucked from liquid source until access pressure reaches an approximately atmospheric level or opening the first bridging valve and the second bridging valve to create connection between withdrawal conduit and return conduit and normalize pressure; then
- keeping the first bridging valve closed, closing the second withdrawal valve and keeping the access valve, the second bridging valve and the first withdrawal valve open to enable liquid from liquid source to flush the vascular access of the patient backwards, to dislodge catheter tip from vessel's wall.

[0067] In a 42nd aspect according to the previous aspect 40, said task or the method for diverting a flow of liquid and/or blood comprises the following steps:

- optionally, opening the first bridging valve and the access valve and closing the first withdrawal valve and the second withdrawal valve and a monitor valve on the blood return line (located between the apparatus and the add-on module) while the return valve is open and the second bridging valve is closed, to flush with liquid at least part of the return conduit;
- optionally, closing the first bridging valve and the second withdrawal valve and opening the second bridging valve while the return valve, the access valve and the first withdrawal valve are open, to flush with liquid at least part of the withdrawal conduit;
- closing the return valve, the first withdrawal valve and the access valve and opening the second withdrawal valve while the first bridging valve and the second bridging valve are open to recirculate blood in the blood treatment unit of the apparatus.

[0068] In a 43rd aspect according to the previous aspect 40, said task or the method for diverting a flow of liquid and/or blood comprises the following steps:

- closing the first withdrawal valve and opening the second bridging valve and the access valve while the return valve and the second withdrawal valve are open;
- pumping liquid until all blood is returned to the patient;
- closing the return valve and opening the first bridging valve while the second bridging valve is open, the second withdrawal valve is open and the first withdrawal valve is closed, to recirculate liquid in the blood treatment unit of the apparatus.

[0069] In a 44th aspect according to any of the previous aspects 1 to 43, the blood treatment unit comprises a primary chamber and a secondary chamber separated by a semi-permeable membrane, wherein the blood withdrawal line is connected to an inlet of the primary chamber and the blood return line is connected to an outlet of the primary chamber. In particular, the blood treatment unit is part of a blood set of the apparatus.

[0070] In a 45th aspect according to the previous aspect 44, an effluent fluid line is connected to an outlet of the secondary chamber and a dialysis fluid line is connected to an inlet of the secondary chamber and to a dialysis liquid source; optionally, an infusion circuit comprising one or more infusion lines of a replacement fluid is connected to the extracorporeal blood circuit. In particular, the effluent fluid line and the infusion circuit are part of a blood set of the apparatus.

[0071] In a 46th aspect according to any of the previous aspects 1 to 45, each of the blood withdrawal line (6) and the blood return line (7) has a respective end connector configured to be connected to the vascular access of the patient (P).

[0072] In a 47th aspect according to any of the previous aspects 1 to 46, each of the withdrawal conduit (23) and

the return conduit (24) has a respective end counter-connector configured to be coupled or coupled with a respective end connector of the blood withdrawal line (6) and of the blood return line (7).

[0073] In a 48th aspect according to any of the previous aspects 1 to 47, each of the withdrawal conduit (23) and the return conduit (24) has a respective end connector configured to be coupled or coupled with a respective end counter-connector of the vascular access of the patient (P).

DESCRIPTION OF THE DRAWINGS

[0074] Aspects of the invention are shown in the attached drawings, which are provided by way of non-limiting example, wherein:

Figure 1 shows a schematic diagram of an apparatus for extracorporeal treatment of blood comprising an add-on module according to the invention;

Figure 2 shows an enlarged view of the add-on module of Figure 1;

Figure 3 shows another embodiment of the add-on module of the invention;

Figure 4 shows a variant of the add-on module of Figure 2;

Figures 5 to 11 show respective working configurations of the add-on module of Figure 1;

Figures 12 to 15 show flowcharts of respective operating modes of the of the add-on module of the invention.

DETAILED DESCRIPTION

[0075] Non-limiting embodiments of an add-on module - which may implement innovative aspects of the invention - for an apparatus 1 for extracorporeal treatment of blood are shown in Figures 2, 3 and 4. In below description and in Figures 2, 3 and 4 same components are identified by same reference numerals.

[0076] An apparatus for the extracorporeal treatment of blood 1 is represented in Figure 1. The apparatus 1 of Figure 1 comprises a blood treatment unit 2 (such as a hemofilter, an ultrafilter, an hemodiafilter, a dialyzer, a plasmafilter and the like) having a primary chamber 3 and a secondary chamber 4 separated by a semi-permeable membrane 5. Depending upon the treatment, the semi-permeable membrane 5 of the blood treatment unit 2 may be selected to have different properties and performances.

[0077] A blood withdrawal line 6 is connected to an inlet of the primary chamber 3 and a blood return line 7 is connected to an outlet of the primary chamber 3. In use, the blood withdrawal line 6 and the blood return line 7 are connected to a needle or to a catheter or other access device 8 which is then placed in fluid communication with the patient "P" vascular system, such that blood may be withdrawn through the blood withdrawal

line 6, flown through the primary chamber 3 and then returned to the patient's vascular system through the blood return line 7. An air separator, such as a deaeration chamber 9, may be present on the blood return line 7. Moreover, a monitor valve 10 may be present on the blood return line 7, downstream the deaeration chamber 9.

[0078] The blood flow through the blood lines is controlled by a blood pump 11, for instance a peristaltic blood pump, acting either on the blood withdrawal line 6 or on the blood return line 7. The embodiment of Figure 1 shows the blood pump 11 coupled to a pump section of the withdrawal line 6. A control unit 100 is connected and controls the blood pump 11 to regulate a blood flow rate.

[0079] An effluent fluid line 12 or spent dialysate line may be connected, at one end, to a fluid outlet of the secondary chamber 4 and, at its other end, to a waste which may be a discharge conduit or an effluent fluid container 13 collecting the effluent fluid extracted from the secondary chamber 4. An effluent pump 14 that operates on the effluent fluid line 13 under the control of the control unit 100 to regulate a flow rate of the effluent fluid through the effluent fluid line.

[0080] The apparatus of Figure 1 includes a dialysis fluid line 15 connected at one end with a fresh dialysis liquid source 16 and at its other end with a fluid inlet of the secondary chamber 4 of the treatment unit 2 for supplying fresh dialysis liquid to the secondary chamber 4. A dialysis fluid pump 17 is operative on the dialysis fluid line 15 under the control of the control unit 100 to supply fluid from the dialysis liquid source 16 to the secondary chamber 4 and to regulate the flow rate of the dialysis liquid.

[0081] The embodiment of Figure 1 further presents an infusion line 18 connected to the blood withdrawal line 6 between the blood pump 11 and the treatment unit 2. This infusion line 18 supplies replacement fluid from an infusion fluid container 19 connected at one end of the infusion line 18. Note that, alternatively or in addition to the infusion line 18, the apparatus of Figure 1 may include a post-dilution fluid line (not shown) connecting an infusion fluid container to the blood return line 7 and/or a pre-blood pump infusion line 18' with its own pre-blood pump infusion fluid container 19'. Furthermore, an infusion pump 20 operates on the infusion line 18 and an infusion pump 20' operates on the pre-blood pump infusion line 18' to regulate respective flow rates through the infusion lines 18, 18'. Also the infusion pumps 20, 20' are operative under the control of the control unit 100.

[0082] The effluent fluid line 12, the dialysis fluid line 15 and the secondary chamber 4 of the blood treatment unit 2 are part of a fluid circuit of the apparatus 1. The blood withdrawal line 6, the blood return line 7, the primary chamber 3 of the treatment unit 2 form part of an extracorporeal blood circuit of the apparatus 1. The infusion lines 18, 18' form part of an infusion circuit of the apparatus 1.

[0083] The control unit 100 may comprise a digital

processor (CPU) with memory (or memories), an analogical type circuit, or a combination of one or more digital processing units with one or more analogical processing circuits. In the present description and in the claims it is indicated that the control unit 100 is "configured" or "programmed" to execute steps: this may be achieved in practice by any means which allow configuring or programming the control unit 100. For instance, in case of a control unit 100 comprising one or more CPUs, one or more programs are stored in an appropriate memory: the program or programs containing instructions which, when executed by the control unit 100, cause the control unit 100 to execute the steps described and/or claimed in connection with the control unit 100. Alternatively, if the control unit 100 is of an analogical type, then the circuitry of the control unit 100 is designed to include circuitry configured, in use, to process electric signals such as to execute the control unit 100 steps herein disclosed.

[0084] The control unit 100 may also be operatively connected to sensors (like flow sensors and/or pressure sensors) on the blood circuit and/or fluid circuit and/or infusion circuit. The control unit 100 is also operatively connected to clamps and valves, like the monitor valve 10. The control unit 100 may also be connected to a user interface, not shown, for instance a graphic user interface, which receives operator's inputs and displays the apparatus outputs. For instance, the graphic user interface may include a touch screen, a display screen and hard keys for entering user's inputs or a combination thereof. During extracorporeal blood treatment, the control unit 100 is configured to control at least the pumps 11, 14, 17, 20, 20' to make sure that a prefixed patient net fluid removal is achieved in the course of a treatment time, as required by a prescription provided to the control unit 100, e.g. via the user interface.

[0085] The apparatus 1 comprises a main portion 22 comprising at least a casing for the control unit 100, the control unit 100, the user interface, the blood pump 11, the effluent pump 14, the dialysis fluid pump 17, the infusion pumps 20, 20' and devices to mount a disposable set (comprising the blood treatment unit 2, the extracorporeal blood circuit, the infusion circuit and the fluid circuit) to the main portion 22.

[0086] The apparatus for the extracorporeal treatment of blood 1 shown in Figure 1 further comprises an add-on module 21 which is configured to be placed in-line between the main portion 22 of the apparatus 1 and the vascular access of a patient "P", in particular the access device 8 (e.g. a needle or a catheter) placed in fluid communication with the patient "P" vascular system. The add-on module 21 may be placed in-line on the withdrawal line 6 and on the return line 7 and closer to the access device 8 than to the main portion 22 of the apparatus 1 for extracorporeal treatment of blood. The add-on module 21 may be disposable, at least in part. The add-on module 21 comprises a substantially H-shaped conduits assembly comprising a withdrawal conduit 23, a return conduit

24 and a bridging conduit 25 connecting the withdrawal conduit 23 to the return conduit 24. Each of the withdrawal conduit 23, the return conduit 24 and the bridging conduit 25 of the embodiments shown in the annexed Figures is a straight plastic tube. The withdrawal conduit 23 is parallel to the return conduit 24 while the bridging conduit 25 is perpendicular to the withdrawal conduit 23 and to the return conduit 24.

[0087] The withdrawal conduit 23 has a first extremity 23a and an opposite second extremity 23b each provided with a quick connector, such as a Luer connector, to allow easy and quick connection/disconnection to/from the remaining portions of the withdrawal line 6. The first extremity 23a is connected or configured to be connected to a portion of the withdrawal line 6 comprising the pump section coupled to the blood pump 11. The second extremity 23b is connected or configured to be connected to a portion of the withdrawal line connected to the access device 8. The return conduit 24 has a first extremity 24a and an opposite second extremity 24b each provided with a quick connector, such as a Luer connector, to allow easy and quick connection/disconnection to/from the remaining portions of the return line 7. The first extremity 24a is connected or configured to be connected to a portion of the return line 7 comprising the deaeration chamber 9 and the monitor valve 10. The second extremity 24b is connected or configured to be connected to a portion of the return line 7 connected to the access device 8.

[0088] The bridging conduit 25 has a first extremity 25a forming a junction to the withdrawal conduit 23 and an opposite second extremity 25b forming a junction to the return conduit 24. For instance, the bridging conduit 25, the withdrawal conduit 23 and the return conduit 24 are connected through T-connectors. The withdrawal conduit 23 comprises two branches connected to the T-connector. A branch comprising the first extremity 23a and a branch comprising the second extremity 23b. The return conduit 24 comprises two branches connected to the T-connector. A branch comprising the first extremity 24a and a branch comprising the second extremity 24b.

[0089] A plurality of valves (e.g. clamps) operate on the withdrawal conduit 23, on the return conduit 24 and on the bridging conduit 25 and are configured to divert a flow of liquid and/or blood without disconnecting the patient "P".

[0090] The add-on module 21 of the embodiments of Figures 1, 2 and 4 to 11 comprises a first withdrawal valve 26 and a second withdrawal valve 27 operating on the withdrawal conduit 23. The first withdrawal valve 26 is placed upstream, with respect to a flow of blood during treatment (flowing from the second extremity 23b to the first extremity 23a of the withdrawal conduit 23), the junction of the bridging conduit 25 to said withdrawal conduit 23 and the second withdrawal valve 27 is placed downstream, with respect to said flow of blood during treatment, the junction of the bridging conduit 25 to said withdrawal conduit 23. As disclosed in Figure 2, the first withdrawal valve 26 and the second withdrawal valve 27 are

placed on opposite sides with respect to the T-connector joining the bridging conduit 25 to the withdrawal conduit 23.

[0091] The add-on module 21 of the embodiments of Figures 1, 2 and 4 to 11 comprises a single return valve 28 operating on the return conduit 24. The return valve 28 is placed downstream the junction of the bridging conduit 25 to the return conduit 24 with respect to a flow of blood during treatment (flowing from the first extremity 24a to the second extremity 24b of the return conduit 24). As disclosed in Figure 2, the return valve 28 is placed at a side of the T-connector joining the bridging conduit 25 to the return conduit 24 and on the branch comprising the second extremity 24b of said return conduit 24.

[0092] In a variant embodiment, not shown, a first return valve and a second return valve operate on the return conduit 24 and are placed on opposite sides with respect to the T-connector joining the bridging conduit 25 to the return conduit 24, similar to the first withdrawal valve 26 and the second withdrawal valve 27. The return valve placed upstream the junction of the bridging conduit 25 to the return conduit 24 with respect to the flow of blood during treatment may perform the function of the monitor valve 10. The add-on module 21 of the embodiments of Figures 1, 2 and 4 to 11 comprises a first bridging valve 29 and a second bridging valve 30 operating on the bridging conduit 25. The first bridging valve 29 is placed closer to the return conduit 24 (closer than the second bridging valve 30) and the second bridging valve 30 is placed closer to the withdrawal conduit 23 (closer than the first bridging valve 29).

[0093] The bridging conduit 25 comprises a first branch having the first extremity 25a and a second branch having the second extremity 25b. The first branch and the second branch are connected to each other through a T-connector delimiting also an access point 31 suitable to connect a liquid source. The first bridging valve 29 is placed on the second branch bridging conduit 25 and the second bridging valve 30 is placed on the first branch of the bridging conduit 25. The access point 31 is located between the first bridging valve 29 and the second bridging valve 30.

[0094] A stretch of tubing departs from the access point 31 and is provided with an access valve 32. The stretch of tubing may be connected to a liquid source 33, like a syringe, e.g. of 50 ml, or a bag, e.g. of 500 ml. The liquid of said liquid source may be saline.

[0095] In the variant embodiment of Figure 3, the add-on module 21 comprises a single bridging valve 29' operating on the bridging conduit 25 and does not comprise any access point 31. In the variant embodiment of Figure 4, the add-on module 21 further comprises (in addition with respect to the embodiment of Figure 3) a further access point 31' on the return conduit 24, e.g. for calcium infusion. The further access point 31' is placed on the branch comprising the second extremity 24b and may be connected to a bag of the apparatus.

[0096] The substantially H-shaped conduits assembly

and the plurality of valves 26, 27, 28, 29, 30, 31 are mounted on a holder 34 which may be shaped like a plate provided with seats, or other holding devices, configured to accommodate the substantially H-shaped conduits assembly and the plurality of valves 26, 27, 28, 29, 30, 31. In the embodiments of Figures 1, 2 and 4 to 11, the holder 34 comprises a seat, or other holding device to hold the syringe 33, and a spring 35 for pressurizing the syringe 33 and ejecting the fluid contained therein through the access point 31.

[0097] The add-on module 21 may also comprise one or more sensors (e.g. pressure sensor, flowmeter, air detector, etc.), not shown, active on the H-shaped conduits assembly, i.e. on the return conduit 24 and/or on the withdrawal conduit 23, on the bridging conduit 25. The plurality of valves 26, 27, 28, 29, 30, 31 and the sensor/s are operatively connected or connectable to the control unit 100 of the apparatus 1 and/or to a control unit of the add-on module 21 which may be slaved to the control unit 100 of the apparatus 1. Said control unit/s is/are configured for commanding, optionally automatically, the configurations of the plurality of valves 26, 27, 28, 29, 30, 31. The valves 26, 27, 28, 29, 30, 31 and/or the control unit of the add-on module 21 may be connected to the control unit 100 of the apparatus 1 through a wired or wireless communication device.

[0098] The add-on module 21 comprises a power supply to power the valves 26, 27, 28, 29, 30, 31 and/or the sensor/s and/or control unit or said valves 26, 27, 28, 29, 30, 31 and/or the control unit of the add-on module 21 may be connected to a power supply of the apparatus 1 to be powered by said apparatus 1.

[0099] The add-on module 21 may be a portable module and/or comprises an attachment device configured to install said add-on module on another element, optionally in a removable manner, e.g. to clothing of a patient "P" or to a bed for the patient "P" or to a main portion of the apparatus for extracorporeal treatment of blood. The lengths of the portion of the return line 7 comprising the deaeration chamber 9 and the monitor valve 10 and of the portion of the withdrawal line 6 comprising the pump section coupled to the blood pump 11 are such to place the add-on module close to the patient "P".

[0100] In use and according to a method of the invention for diverting a flow of liquid and/or blood in the apparatus 1, before treatment of the patient "P", the blood circuit is primed and the control unit 100 controls the valves 26, 27, 28, 29, 30, 31 to allow priming the withdrawal conduit 23, the return conduit 24 and the bridging conduit 25, using either solution bags of the apparatus 1 or saline from the liquid source 33 connected to the access point 31.

[0101] During patient treatment (Figures 5 and 12), when blood flows from patient "P" through the withdrawal line 6, into the primary chamber 3 of the blood treatment unit 2 and then back into the patient "P" through the return line 7, the control unit 100 controls the valves 26, 27, 28, 29, 30, 31 to configure said valves 26, 27, 28, 29, 30, 31

in a treatment configuration. In the treatment configuration, the first bridging valve 29, the second bridging valve 30 and the access valve 32 are closed, the first withdrawal valve 26, the second withdrawal valve 27 and the return valve 28 are open.

[0102] During patient treatment, since blood may stagnate at the closed first bridging valve 29 and the second bridging valve 30, in order to prevent coagulation, the first bridging valve 29 and the second bridging valve 30 and the access valve 32 are opened regularly (intermittently), to flush the bridging conduit 25 with fluid and prevent coagulation. According to a variant of the method, the first bridging valve 29 and the second bridging valve 30 are opened regularly (intermittently) while the access valve 31 is closed, to flush the bridging conduit 25 with blood, creating a short recirculation and preventing coagulation (Figure 12).

[0103] In case of Access Extremely Negative (AEN) alarm, the blood pump 11 is stopped, the second bridging valve 30 and the access valve 32 are opened to enable saline to be sucked from the syringe 33 until access pressure reaches an approximately atmospheric level or the first bridging valve 29 and the second bridging valve 30 are both opened to create connection between the withdrawal conduit 23 and the return conduit 24 and to normalize pressure. After the access pressure got closer to the atmospheric level, the first bridging valve 29 is kept closed, the second withdrawal valve 27 is closed while the access valve 32, the second bridging valve 30 and the first withdrawal valve 26 are kept open. This way, the fluid from syringe 33 flushes the vascular access of the patient "P" backwards to help dislodge the catheter tip from vessel's wall (Figures 6 and 13).

[0104] According to another possible action to solve an AEN alarm, the first withdrawal valve 26 and the second withdrawal valve 27 are closed while the other valves are open. The blood pump 11 is controlled to turn in order to increase the access negative pressure till a defined value and then stopped. Then the first withdrawal valve 26 and the second withdrawal valve 27 are opened to create a sudden negative pressure peak in the catheter's access way to move or break a clot.

[0105] If these attempts fail, the control unit 100 controls the plurality of valves to 26, 27, 28, 29, 30, 31 to engage blood recirculation, while notifying the staff that action is required (moving the patient "P", caring for the vascular access, etc.). Prior to enabling blood recirculation, flushing is needed in the return conduit 24 and withdrawal conduit 23 to avoid clotting and to enable patient reconnection after staff intervention. To this aim, the branch of the return conduit 24 comprising the second extremity 24b is flushed with fluid by closing the second bridging valve 30 and the monitor clamp 10 while the first bridging valve 29, the first withdrawal valve 26, the second withdrawal valve 27, the return valve 28 and the access valve 32 are open and fluid from the syringe 33 is injected (Figures 7 and 14).

[0106] The branch of the withdrawal conduit 6 having

the second extremity 23b is then flushed. The first bridging valve 29 and the second withdrawal valve 27 are closed, the second bridging valve 30, the first withdrawal valve 26 and the access valve 32 are open and saline from the syringe 33 is injected (Figures 8 and 14).

[0107] The blood recirculation starts with the return valve 28 closed, the first withdrawal valve 26 closed, the second withdrawal valve 27 open and the first and second bridging valves 29, 30 open, so that blood recirculates in the blood treatment unit 2 of the apparatus 1 and staff intervention is executed (Figures 9 and 14). At the end of the treatment, with blood return to the patient "P", saline recirculation starts. With the first withdrawal valve 26 and the first bridging valve 29 closed and the second bridging valve 30, the return valve 28, the second withdrawal valve 27 and the access valve 32 open, saline is pumped by the blood pump 11 until all blood is returned to the patient "P". Then, the return valve 28 is closed and the first bridging valve 29 is opened while the second bridging valve 30 is still open, the second withdrawal valve 27 is open and the first withdrawal valve 26 is closed, to recirculate liquid in the blood treatment unit 2 of the apparatus 1 (Figures 11 and 15).

[0108] While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the scope of the appended claims.

Claims

1. Add-on module for an apparatus for extracorporeal treatment of blood, wherein the apparatus (1) comprises:

- a blood treatment unit (2);
- an extracorporeal blood circuit coupled to the blood treatment unit (2) and comprising a blood withdrawal line (6) and a blood return line (7) connectable to a vascular access of a patient (P);
- a blood pump (11) configured to be coupled to a pump section of the extracorporeal blood circuit;

wherein the add-on module (21) is configured to be placed in-line between a main portion (22) of the apparatus (1) and the vascular access of the patient (P) and comprises:

- a substantially H-shaped conduits assembly comprising a withdrawal conduit (23), a return conduit (24) and a bridging conduit (25) connecting the withdrawal conduit (23) to the return conduit (24); wherein the withdrawal conduit (23) is

connectable upstream and downstream to the withdrawal line (6), wherein the return conduit (24) is connectable upstream and downstream to the return line (7);

- a plurality of valves (26, 27, 28, 29, 30, 31), optionally clamps, operating on the withdrawal conduit (23), on the return conduit (24) and on the bridging conduit (25) and configured to divert a flow of liquid and/or blood without disconnecting the patient (P).

2. The add-on module according to claim 1, wherein the withdrawal conduit (23) is substantially parallel to the return conduit (24) and wherein the bridging conduit (25) is transversal, optionally perpendicular, to the withdrawal conduit (23) and to the return conduit (24).
3. The add-on module according to claim 1 or 2, wherein at least one of the withdrawal conduit (23), the return conduit (24) and the bridging conduit (25) is straight.
4. The add-on module according to any of claims 1 to 3, wherein the plurality of valves (26, 27, 28, 29, 30, 31) comprises at least a withdrawal valve (26, 27) operating on the withdrawal conduit (23), at least a return valve (28) operating on the return conduit (24) and at least a bridging valve (29, 30) operating on the bridging conduit (25).
5. The add-on module according to claim 4, wherein said at least a withdrawal valve (26, 27) comprises a first withdrawal valve (26) and a second withdrawal valve (27) operating on the withdrawal conduit (23), wherein the first withdrawal valve (26) and the second withdrawal valve (27) are placed on opposite sides with respect to a junction of the bridging conduit (25) to the withdrawal conduit (23), wherein the first withdrawal valve (26) is placed upstream, with respect to a flow of blood during treatment, the junction of the bridging conduit (25) to said withdrawal conduit (23), wherein the second withdrawal valve (27) is placed downstream, with respect to the flow of blood during treatment, the junction of the bridging conduit (25) to said withdrawal conduit (23).
6. The add-on module according to claim 4 or 5, wherein the return valve (28) is placed downstream a junction of the bridging conduit (25) to the return conduit (24) with respect to a flow of blood during treatment.
7. The add-on module according to claim 4 or 5 or 6, wherein said at least a bridging valve (29, 30) comprises a first bridging valve (29) and a second bridging valve (30) operating on the bridging conduit (25), wherein the first bridging valve (29) is placed closer to the return conduit (24) and the second bridging

valve (30) is placed closer to the withdrawal conduit (23), wherein the bridging conduit (25) has an access point (31) located between the first bridging valve (29) and the second bridging valve (30) and suitable to connect a liquid source (33), optionally a saline source, optionally a syringe or a bag, or optionally a citrate source coming from the apparatus (1) for extracorporeal blood treatment.

8. The add-on module according to claim 7, comprising a liquid source, optionally a syringe or a bag, connected or connectable to the access point (31).
9. The add-on module according to any of claims 1 to 8, comprising a holder (34) configured to hold the substantially H-shaped conduits assembly and the plurality of valves (26, 27, 28, 29, 30, 31) and, optionally when claim 9 depends on claim 8, the liquid source (33).
10. The add-on module according to any of claims 4 to 8, wherein the plurality of valves (26, 27, 28, 29, 30, 31) is configured to be arranged at least in a treatment configuration, in which said at least a withdrawal valve (26, 27) and said at least a return valve (28) are open and said at least a bridging valve (29, 30) is closed, to perform treatment of the patient (P).
11. The add-on module according to claim 6 when depending on claim 5, wherein the plurality of valves (26, 27, 28, 29, 30, 31) is configured to be arranged at least in a recirculation configuration, in which the return valve (28) is closed, the first withdrawal valve (26) is closed, the second withdrawal valve (27) is open and said at least a bridging valve (29, 30) is open, so that blood or liquid recirculates in the blood treatment unit (2) of the apparatus (1) without disconnecting the patient (P).
12. The add-on module according to claim 7 when dependent on claim 5, wherein the plurality of valves (26, 27, 28, 29, 30, 31) is configured to be arranged in a return branch flushing configuration, in which the first bridging valve (29) is open, the second bridging valve (30) is closed and the liquid source (33) is connected to the access point (31) to inject liquid and flush a branch of the return conduit (24) placed downstream a junction of the bridging conduit (25) to the return conduit (24).
13. The add-on module according to claim 12, wherein the plurality of valves (26, 27, 28, 29, 30, 31) is configured to be arranged in a withdrawal branch flushing configuration, in which the first bridging valve (29) is closed, the second bridging valve (30) is open, the second withdrawal valve (27) is closed and the liquid source (33) is connected to the access point (31) to inject liquid and flush a branch of the withdrawal con-

duit (23) placed upstream a junction of the bridging conduit (25) to the withdrawal conduit (23) .

14. The add-on module according to any of claims 10 to 13, wherein the valves of the plurality of valves (26, 27, 28, 29, 30, 31) are operatively connected or connectable to a control unit (100), optionally of the apparatus (1) for extracorporeal treatment of blood, or wherein the add-on module (21) comprises a control unit operatively connected to the valves of the plurality of valves (26, 27, 28, 29, 30, 31); wherein the control unit (100) is configured for commanding, optionally automatically, the configurations of the plurality of valves (26, 27, 28, 29, 30, 31) .
15. A blood set for an apparatus for extracorporeal treatment of blood, the blood set comprising:

a blood treatment unit (2);
an extracorporeal blood circuit coupled to the blood treatment unit (2) and comprising a blood withdrawal line (6) and a blood return line (7) connectable to a vascular access of a patient (P), optionally each of the blood withdrawal line (6) and the blood return line (7) having a respective end connector configured to be connected to the vascular access of the patient (P);
an add-on module (21) according to one of the preceding claims 1 to 14, wherein the add-on module (21) is placed or is configured to be placed in-line between the blood set of the apparatus (1) for extracorporeal treatment of blood and the vascular access of the patient (P), in particular the withdrawal conduit (23) and the return conduit (24) having a respective end counter-connector configured to be coupled or coupled with the endo connector of the blood withdrawal line (6) and of the blood return line (7).

FIG.1

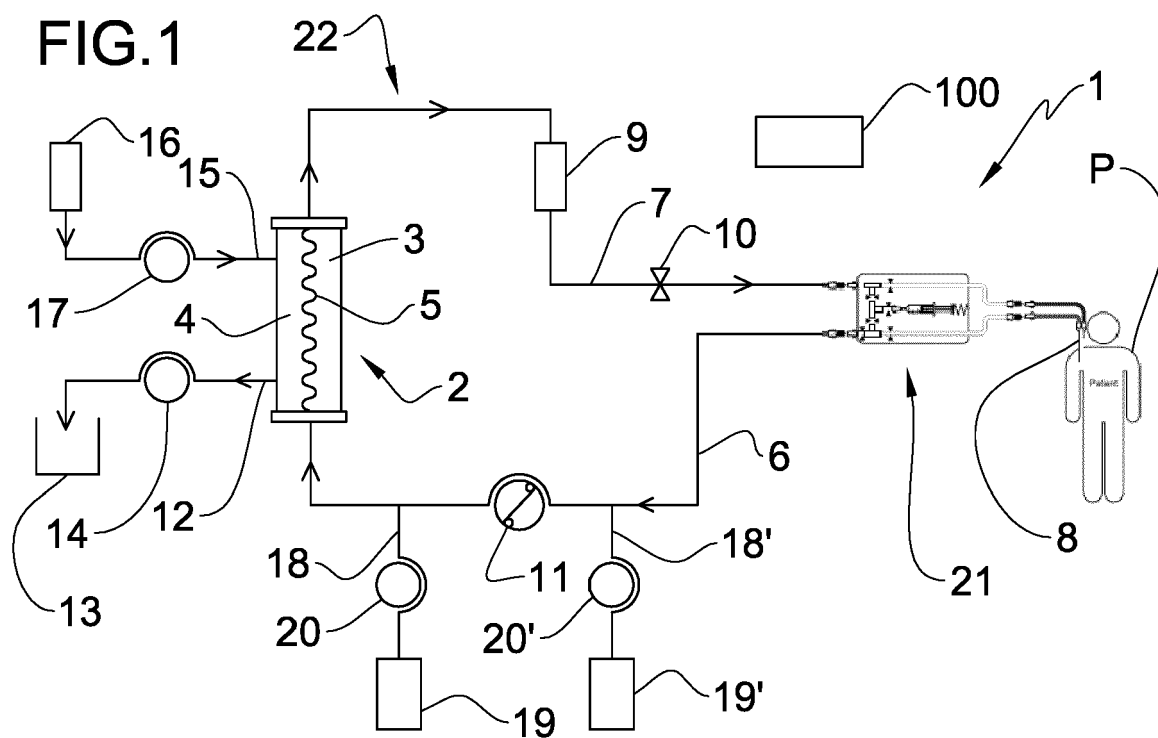


FIG.2

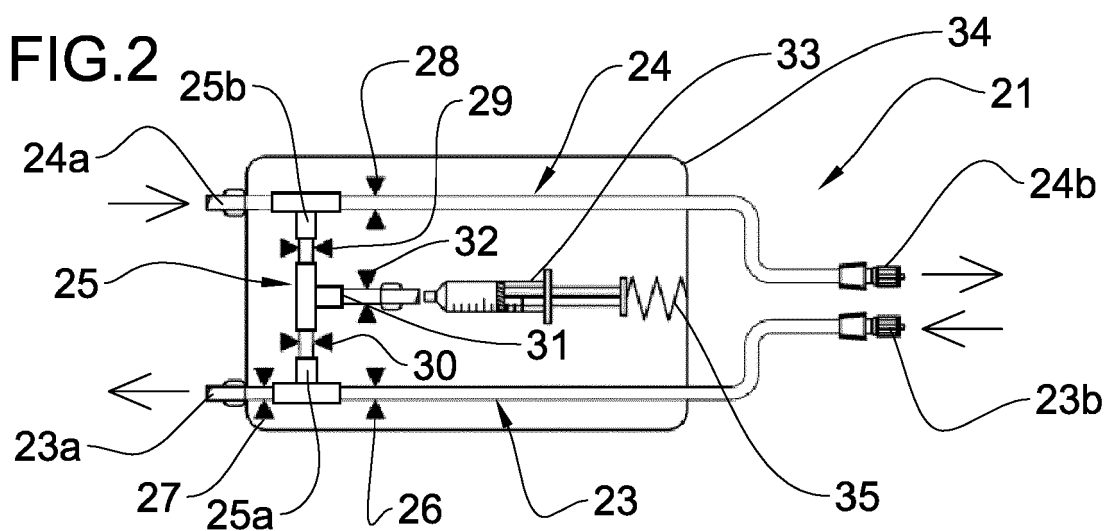


FIG.3

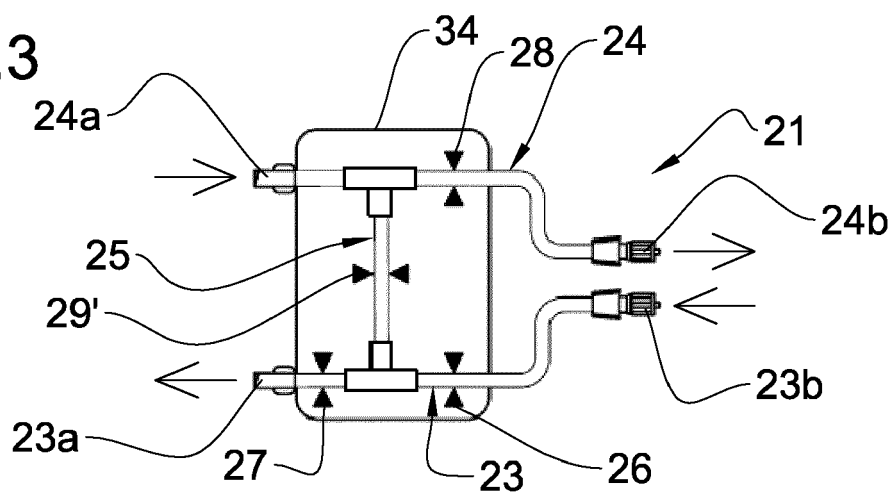


FIG.4

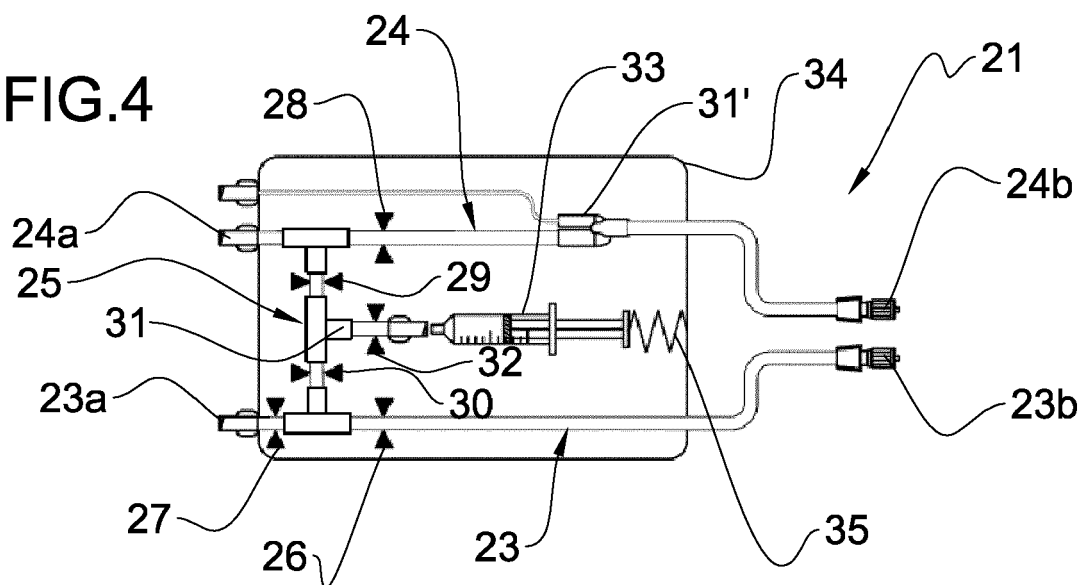


FIG.5

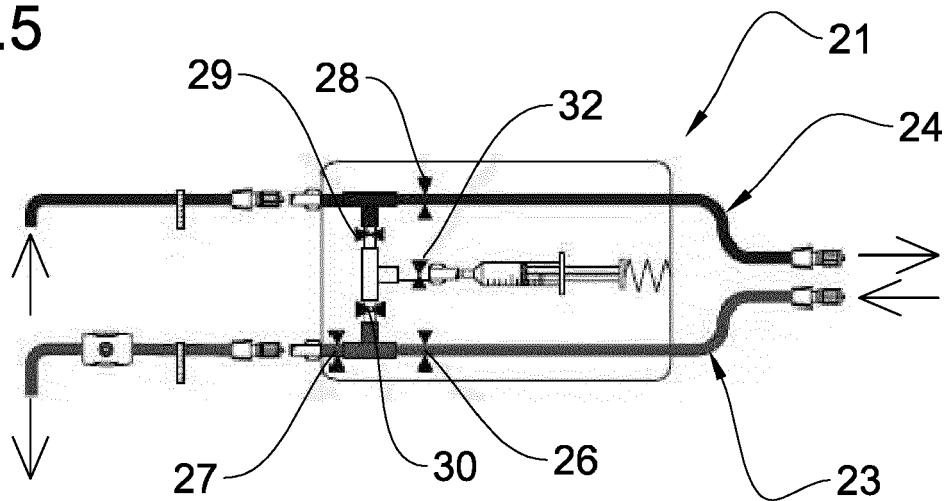


FIG.6

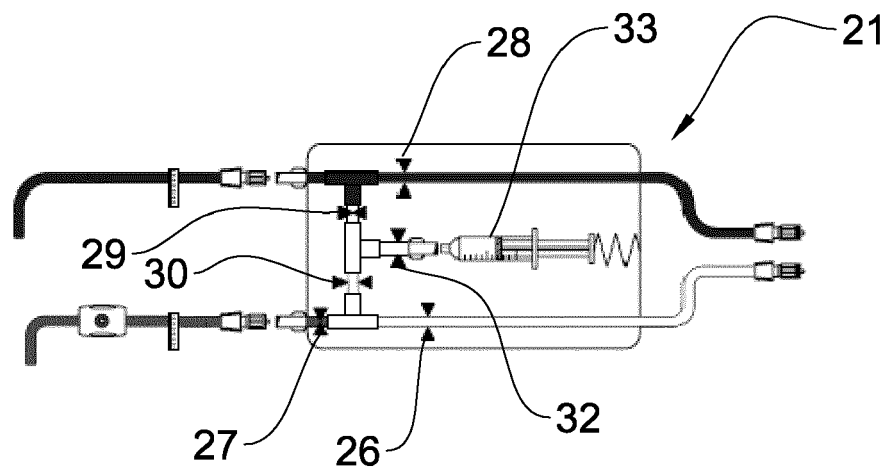


FIG.7

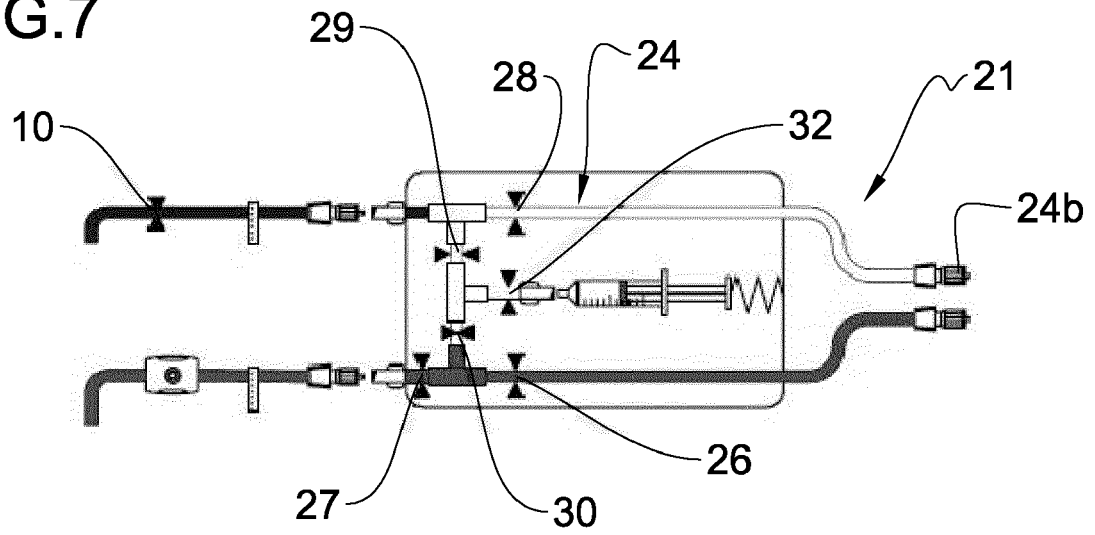


FIG.8

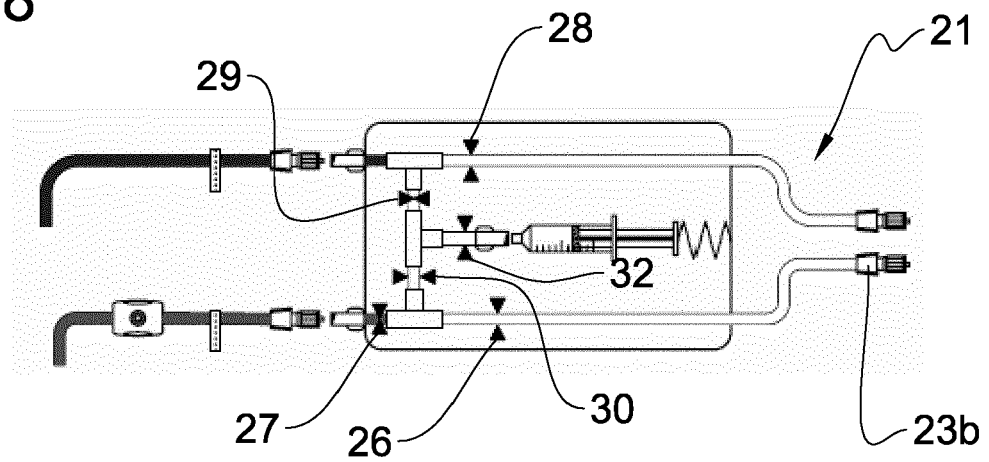


FIG.9

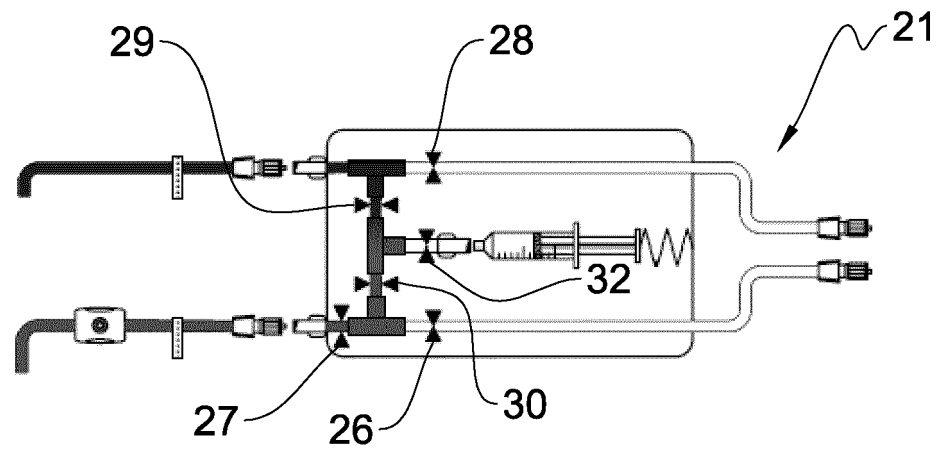


FIG.10

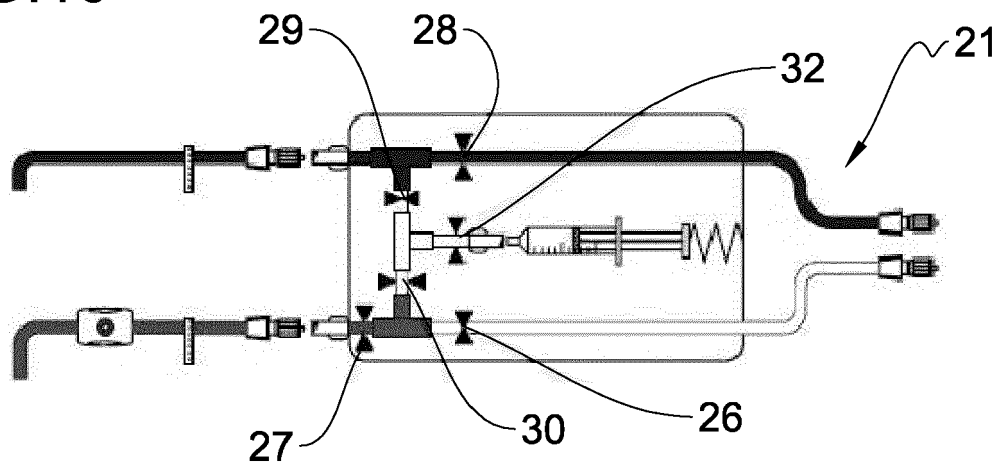


FIG.11

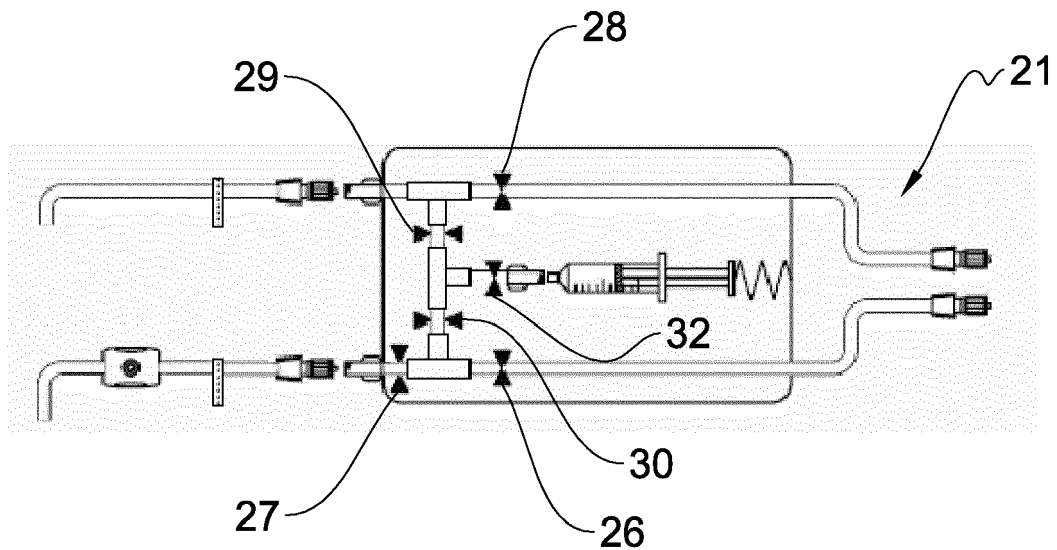


FIG.12

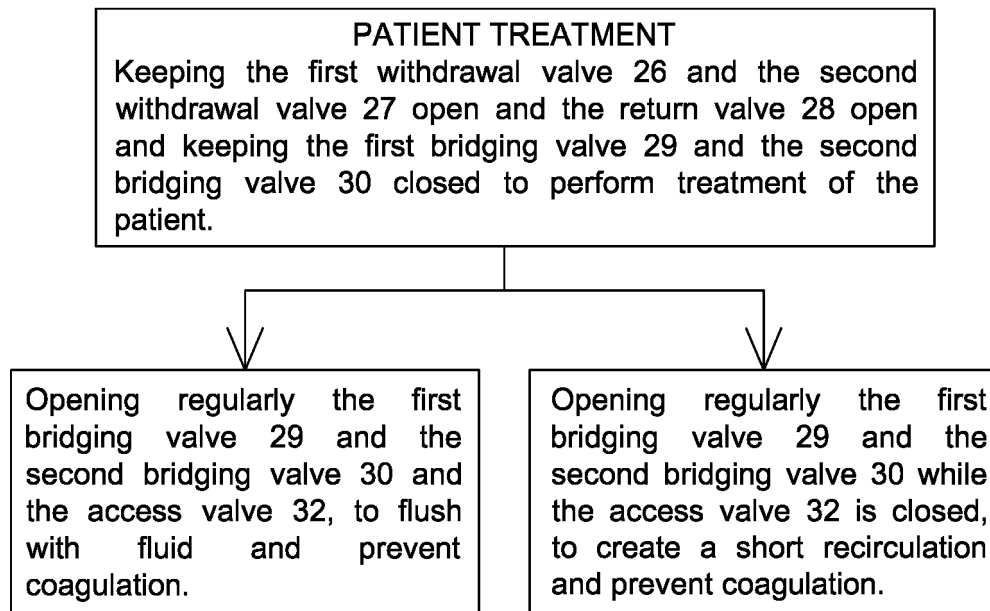


FIG.13

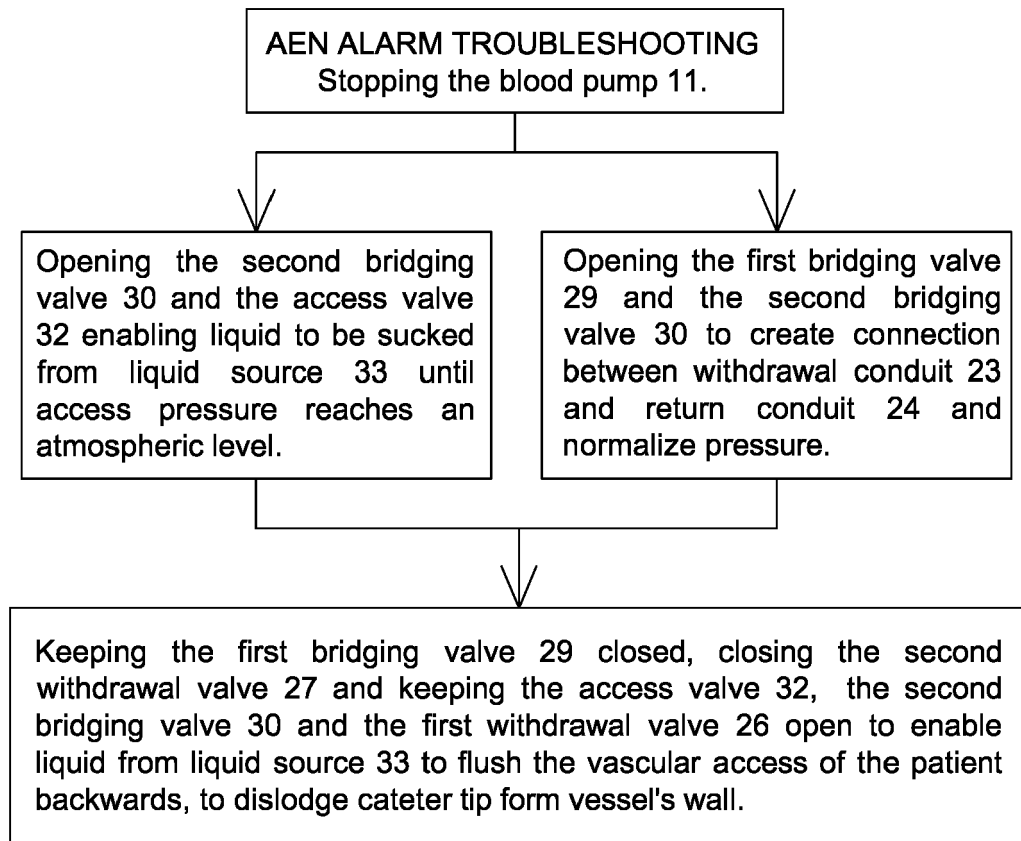


FIG.14

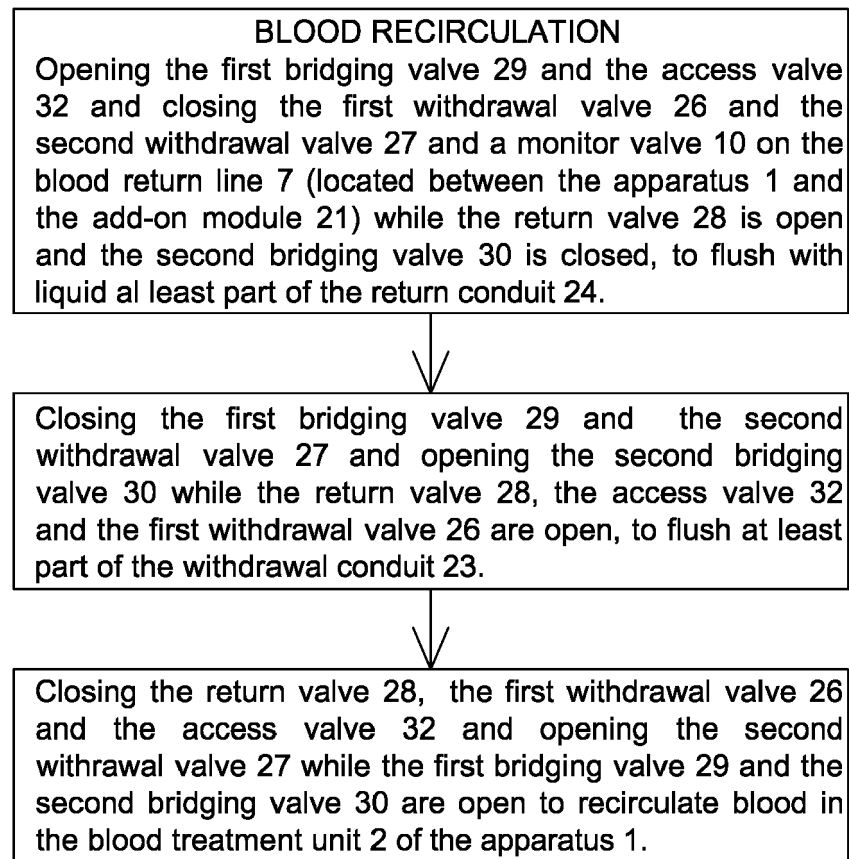
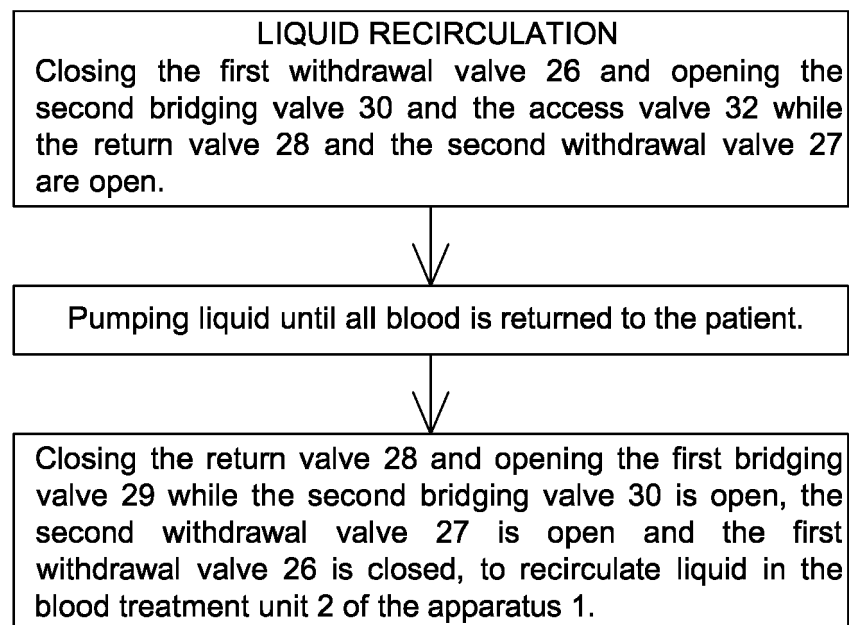


FIG.15





EUROPEAN SEARCH REPORT

Application Number
EP 19 21 6147

5

10

15

20

25

30

35

40

45

50

55

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2011/230772 A1 (KOBALL SEBASTIAN [DE] ET AL) 22 September 2011 (2011-09-22) * the whole document * * paragraphs [0023] - [0024], [0027], [0028], [0040]; claims 23-28; figure 1 *	1-4,6,9,10,14,15	INV. A61M1/36 A61M39/10
X	US 2013/110028 A1 (BACHMANN ANGELIKA [DE] ET AL) 2 May 2013 (2013-05-02) * the whole document * * paragraphs [0137] - [0142]; claim 48; figures 1, 3 *	1-4,6,10,14,15	
X	FR 2 889 451 A1 (MONTILLIER PHILIPPE [FR]) 9 February 2007 (2007-02-09) * the whole document * * page 1, line 4; figures 5a, 5b * * page 5, line 14 - line 20 * * page 6, line 11 - line 18 * * page 9, line 9 - line 14 *	1-4,6,9,10,14,15	
A	WO 03/006944 A2 (NXSTAGE MEDICAL INC [US]; BRUGGER JAMES [US]; BURBANK JEFFREY [US]) 23 January 2003 (2003-01-23) * the whole document * * figure 10 *	1-15	TECHNICAL FIELDS SEARCHED (IPC) A61M
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 5 June 2020	Examiner Pinta, Violaine
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

EPO FORM 1503 03.02 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 19 21 6147

5

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

05-06-2020

10

15

20

25

30

35

40

45

50

55

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011230772 A1	22-09-2011	DE 102008059379 A1	02-06-2010
		EP 2367473 A1	28-09-2011
		US 2011230772 A1	22-09-2011
		WO 2010060951 A1	03-06-2010

US 2013110028 A1	02-05-2013	DE 102010020838 A1	24-11-2011
		EP 2571566 A1	27-03-2013
		US 2013110028 A1	02-05-2013
		WO 2011144315 A1	24-11-2011

FR 2889451 A1	09-02-2007	NONE	

WO 03006944 A2	23-01-2003	AT 480275 T	15-09-2010
		AU 2002326340 A1	29-01-2003
		EP 1425063 A2	09-06-2004
		JP 4118233 B2	16-07-2008
		JP 2005525129 A	25-08-2005
		US 2003009123 A1	09-01-2003
		US 2004243046 A1	02-12-2004
		WO 03006944 A2	23-01-2003

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 3626938 A [0010]
- US 5894011 A [0011]